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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176
29156	7590	03/07/2006		
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			EXAMINER HOWARD, SHARON LEE	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



Receipt of the Amendment and the Remarks filed on 11/14/05 have been acknowledged. Applicant please note that the rejection over claims 8-20 claiming the same invention as Claims 8-15,36-48 of U.S. Application No. 10/206,492 has been considered withdrawn. Claims 8-20 remain pending in this application.

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (U.S. Patent No. 5,578,336).

Monte teaches a chewing gum composition consisting of a gum center which comprises layers of coatings, in which one layer is coated with a vitamin (vitamin defines the medicament as claimed by applicant) (see the abstract and cols.3 and 4). Monte discloses sugarless sweeteners, as well as xylitol and maltitol which reads on claim 11. Xylitol and maltitol defines a taste masking agent (see cols.2 and 3). At col.3,

lines 18-23 and col.12, example 29, Monte discloses the coating composition is applied to the gum center in a coating layers.

Monte does not teach the particular amounts of the coating nor the amounts of the taste masking agent.

However, absent a showing in the criticality of the particular amounts, there are no unexpected results, the Monte reference does teach a gum center which is coated with a medicament. Through routine experimentation, the particular amounts can be readily determined by one skilled in the pharmaceutical art.

The expected result would be to provide drug delivery to a gum center product with comprises a medicament in a coating layer.

No claims allowed.

### ***Response to Arguments***

Applicant's arguments filed 11/10/05 have been fully considered but they are not persuasive. Applicant argues that all of the claimed elements are not taught or suggested by *Monte*. For example, in contrast to the present claims, *Monte* fails to disclose or suggest a coating comprising at least 50% by weight of the product. Instead, *Monte* only discloses that its product has coating layers. See, *Monte*, column 2, lines 62-67.

Applicants respectfully disagree with the Patent Office's assertions that the claimed coating limitations are not entitled to any patentable weight. The claimed

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coating levels are not conventionally used in the confectionery industry, and thus, these levels would not be obvious. *Monte* fails to even suggest a product having at least 50% by weight of a coating as required by Claims 8 and 16. In fact, *Monte* fails to suggest the problems that Applicants' invention seeks to overcome. Regardless, Applicants have demonstrated the importance of the claimed coating levels. Conventional consumable centers do not contain a significant amount of coating by weight of the product. Nowhere does *Monte* recognize or successfully employ the benefits of medicament absorption through the oral mucosa. Applicants respectfully submit that Claims 8 and 16 in this Application which currently requires "a consumable center" are patentably distinct from Claim 8 in Application No. 10/206,492 which now requires "a tableted center comprising at least one compressible saccharide or sugar alcohol." Similarly, Claims 8 and 16 are distinct from independent Claim 44 of the 10/206,492 application which currently requires "a center that is defined by at least one excipient" because consumable centers need not contain excipients. Also, in view of the distinctions between the independent claims of the two applications, Applicants respectfully submit that Claims 8-20 do not claim the same invention as Claims 8-15 and 36-48 of U.S. Patent Application No. 10/206,492. Accordingly, Applicants respectfully request that the double patenting rejection of Claims 8-20 under 35 U.S.C. 101 be withdrawn.

In response to applicant's arguments above, the *Monte* reference teaches a gum center comprising coating layers, in which one layer is coated with a vitamin (a vitamin can be defined as a medicament) (see the abstract and cols.3 and 4). Although the

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reference does not teach a tableted center per se, the reference does suggest the teachings of a tableted center comprising a gum center which consists of a layer coated with a vitamin. Also, in particular, Example 1 at column 6 shows the presence of sugar and sugar is a saccharide. Since the coating is a medicament, there is no criticality of 50%. The amount of the medicament depends on the conditions of the disease, including other parameters such as the weight of the patient. Also, Applicants' argument with respect to base claim 8 in both applications are patentably distinct and that Claims 8-20 do not claim the same invention as Claims 8-15,36-48 of U.S. Patent Application No. 10/206,492 have been fully considered and are persuasive.

The rejection is maintained for reasons set forth above and is deemed obvious. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/3/06

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